

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1,5-22,25-33,40-54,58-91,96-97,100-107,225,229-255,282 and 284-300 are pending after entry of the amendments set forth herein.

Claims 1,5-22,25-33,40-54,58-91,96-98,100-107,225,229-255,282 and 284-300 were examined. Claims 1,5-22,25-33,40-54,58-91,96-98,100-107,225,229-255,282 and 284-300 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**The Office Action**

Applicants respectfully request that the Examiner review and verify the numbering of the pending claims at his end, since the Office Action indicated that claims 97 and 98 were rejected, but Applicants believe that claim 98 has been canceled.

Claims 1, 9, 43-45, 106, 298 and 299 were rejected under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., U.S. Patent No. 5,823,956. The Examiner referred to Figures 1-7 and column 8, line 6 to column 17, line 15 as support for the assertion of anticipation. Upon reviewing the portions of Roth et al. identified, Applicants note that Figs. 1-7 are directed primarily to the use of an intracardiac access device that is the subject of the Ross et al. disclosure. Column 8, line 6 to column 17, line 15 describe various devices and methods for performing procedures within the heart such as electrophysiological mapping and ablative treatments. An electrophysiological device described includes a rigid shaft suitable for introduction through the inner lumen of the access device and a deflectable tip attached to the distal end of the shaft. The distal tip may be introduced into a chamber of the heart via the access device and then, after passing through the access device, may be contacted against a site on an interior wall of the heart to perform an electrophysiological procedure. In none of the embodiments described does Roth et al. disclose or suggest delivering ablative energy from within the access device tube or from within any other tubular member, as recited in claim 1.

With regard to claim 106, Roth et al. does not disclose or suggest positioning a pre-shaped distal end portion of a guide catheter proximate to an extended region of tissue to be ablated, locating an ablative device such that an energy delivery portion is located within a least a portion of the guide

catheter and delivering ablating energy from such a position. Should the Examiner disagree, the Examiner is respectfully requested to specifically explain the Examiner's interpretation to the contrary, with specific reference to the Roth et al. disclosure.

Claims 9, 43-45, 298 and 299 each depend from claim 1 and it is respectfully submitted that these claims are therefore allowable over Roth et al. for at least the same reasons provided above with regard to claim 1.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 9, 43-45, 106, 298 and 299 under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., U.S. Patent No. 5,823,956, as being inappropriate.

Claims 1, 9, 43-45, 96, 97, 298 and 299 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404. The Examiner asserted that Lennox et al. teaches the use of a flexible sheath with a window for transmitting radiation to tissue, that Costello et al. teaches the equivalence of stationary and translatable energy applications, and that it would have been obvious to employ the flexible sheath of Lennox et al. in the method of Costello et al. to keep the optic clean.

Applicants respectfully disagree. Costello et al. requires a hollow rigid outer sheath (see column 3, line 1) in order to facilitate insertion and passage of the device up the urethra. It would not have been obvious to replace such a rigid sheath with a flexible one as this would make inserting the device through the urethra considerably more difficult, if not impossible. Further, the rigid outer sheath 22 is used to spread opposed portions of the inner wall 17 of the prostatic urethra, see column 6, lines 35-43. The spreading motion is accomplished by pushing laterally with the rigid instrument 10. If the instrument 10 were modified to replace the rigid sheath 22 with a flexible sheath, as suggested by the Examiner, this spreading function could not be performed.

Accordingly, for at least the above reasons, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 9, 43-45, 96, 97, 298 and 299 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as not being properly combinable as indicated.

Claims 5-8, 10-22, 25-33, 40-42, 46-54, 58-72, 100-107, 225, 229-255, 282, 284-297 and 300 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Cox et al., WO 98/17187. The Examiner asserted that Cox et al. teaches the equivalence of laser, ultrasound microwave and cryosurgical energies

as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pr-shaped, sue of a sheath with a cut out window and various manipulation of a device including ablating around the pulmonary vein, ablating on the epicardium, and position the device in three or more positions. In view of this, the Examiner concluded that it would have been obvious to employ the maze procedure and ablation means of Cox et al. in the combined method of Lennox et al. and Costello et al. or to employ the combined teachings of Lennox et al. and Costello et al. in the method of Cox et al. since Cox et al. teaches no particular form for the non-cryogenic ablation elements.

Applicants respectfully disagree. Costello et al. cannot be modified with the flexible sheath teaching of Lennox et al. suggested by the Examiner since this would destroy the functionality of the Costello et al. device for practicing the method as disclosed, as discussed above. The device and method described by Lennox et al. are explicitly stated to be provided for treating tissue beneath the surface of a target tissue, while preventing substantial damage to the surface tissue, see column 1, lines 64-66. As such, these teachings are not useful for and thus not properly combinable with Cox et al., since practicing of the techniques of Lennox et al. to attempt to perform a Cox-Maze procedure would fail, as ablation must be performed all the way through the wall of tissue, including the surface of the tissue, in order to successfully block conduction. The method of Costello et al. is specific to treatment of the prostate and requires a rigid shaft, as described above. This method is also not well suited to the Cox-maze procedures as described in Cox et al., since a flexible device is required to perform the manipulations described.

Cox et al. employs a plurality of probes for forming lesions on the heart, and this is contrary to the claimed methods of slidably repositioning an ablating element within a tubular member to successively form lesions. The Examiner has indicated that the various claimed ablation energies are equivalent, so there would have been no motivation to vary from the multi-probe technique of Cox et al. when using another source of ablating energy, given such asserted equivalence. Rather, the modification would have been to merely replace the type of ablating surfaces used on each probe and maintain the multi-probe methodology.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 5-8, 10-22, 25-33, 40-42, 46-54, 58-72, 100-107, 225, 229-255, 282, 284-297 and 300 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Cox et al., WO 98/17187, as

being inappropriate.

Claims 70-79 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Swanson et al. It is respectfully submitted that these claims are allowable over the cited references for at least the same reasons provided above with regard to claim 1, since these claims depend from claim 1 and since Lennox et al. and Costello et al. are not properly combinable in the manner suggested by the Examiner for the reasons provided above with regard to claim 1.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 70-79 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Swanson et al., as being inappropriate.

Claims 80-91 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in view of Kesten et al. It is respectfully submitted that these claims are allowable over the cited references for at least the same reasons provided above with regard to claim 1, since these claims depend from claim 1 and since Lennox et al. and Costello et al. are not properly combinable in the manner suggested by the Examiner for the reasons provided above with regard to claim 1.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 80-91 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in view of Kesten et al., as being inappropriate.

## **Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

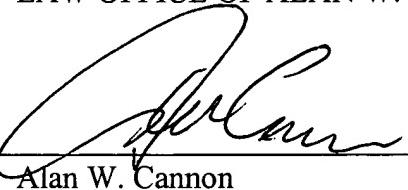
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-117.

Respectfully submitted,

LAW OFFICE OF ALAN W. CANNON

Date: 12/7/05

By:

  
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Alan W. Cannon  
Registration No. 34,977

LAW OFFICE OF ALAN W. CANNON  
834 South Wolfe Road  
Sunnyvale, CA 94086  
Telephone: (408) 736-3554  
Facsimile: (408) 736-3564